REMARKS

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

The rejection of claims 1, 4 and 5 under 35 U.S.C. §112(first paragraph) as for lack of written description is respectfully traversed.

The rejection of claims 1, 4 and 5 under 35 U.S.C. § 112 (first paragraph) for lack of enablement is respectfully traversed.

In order for claims to be enabled, the specification, when filed, must contain sufficient information as to enable one skilled in the art to make and use the claimed invention. (Manual of Patent Examining Procedure ("MPEP") 2164.01). As long as the specification discloses at least on method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, the enablement requirement is satisfied. (In re Fisher, 427 F.2d. 833, 839, 166 USPQ 18, 24 (CCPA 1970); MPEP 2164.01(b)). In determining whether a patent application is in compliance with the enablement requirement, the PTO will consider whether one of ordinary skill in the art could practice the invention without undue experimentation. In re Wands, 858 F.2d. 731, 8 USPQ2d 1400 (Fed. Cir. 1988)).

It is the position of the U.S. Patent and Trademark Office (PTO) (as stated on page 5 of the outstanding office action) that the present specification is not enabling for *in vivo* treatment because *in vitro* modeling systems do not correlate well with the *in vivo* environment. However, one skilled in the art is enabled to use antibodies in a method of treatment of HIV infection both *in vitro* and *in vivo*.

As evidence that *in vitro* modeling systems correlate well with the *in vivo* environment with respect to antibody

treatment for HIV infection (as well as evidence that those skilled in the art could practice the claimed invention both *in vitro* and *in vivo*), Reimann et al., AIDS RES HUM RETROVIRUSES, 13(11):933-43(1997)(abstract), Reimann et al. , AIDS RES HUM RETROVIRUSES, 18(11):747-55(2002)(abstract), Reimann et al. , AIDS RES HUM RETROVIRUSES, 11(4):517-25(1995)(abstract), Reimann et al. , AIDS RES HUM RETROVIRUSES, 9(3):199-207(1993)(abstract) and Boon et al., TOXICOLOGY, 172(3):191-203(2002)(abstract) (copies of full papers to follow) indicate that certain antibodies directed against CD4 could block HIV infection both *in vitro* and *in vivo*. These references show that the *in vitro* results were predictive of *in vivo* results using CD4 antibodies to block HIV infection. Thus, one skilled in the art would accept the *in vitro* model as correlating to *in vivo* success with respect to antibodies to treat HIV. Accordingly, one skilled in the art, with the knowledge contained in the present specification, could practice the present invention. In particular, one skilled in the art, without undue experimentation, could use the methods present in the present specification (page 9, line 23 to page 11, line 15), as well as the knowledge contained in the art to administer antibodies to block HIV infection *in vitro* and *in vivo*.

Further, the fact the experimentation, even if complex, is required does not make it undue, if the art typically engages in such experimentation (MPEP 2164.01).

Accordingly, the rejection is improper and should be withdrawn.

In view of the foregoing, applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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I hereby certify that this document is being deposited with the U.S. Postal Service as first class mail on 11/5/04 under 37 CFR 1.8 and is addressed to the Commissioner for Patent, PO Box 1450, Alexandria, VA 22313-1450

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